

I HEREBY CERTIFY THAT THIS CORRESPONDENCE ALONG WITH ANY ATTACHMENTS IDENTIFIED
HEREIN IS BEING FILED ELECTRONICALLY VIA EFS WEB ON THE DATE IDENTIFIED BELOW.

Date: 4/27/07

Lisa D. Jones



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE
BOARD OF PATENT APPEALS AND INTERFERENCES**

In re patent application

Appellant:	Shlomo Gabbay	Art Unit:	3738
Serial No.:	09/973,609	Examiner:	B. Pellegrino
Filed:	October 9, 2001	Confirmation No.:	8158
Title:	IMPLANTATION SYSTEM FOR IMPLANTATION OF A HEART VALVE PROSTHESIS		

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Following the Notice of Appeal filed on April 27, 2007, Appellant presents this
Appeal Brief.

1. TABLE OF CONTENTS	
2. REAL PARTY IN INTEREST	3
3. RELATED APPEALS AND INTERFERENCES.....	3
4. STATUS OF CLAIMS	3
5. STATUS OF AMENDMENTS.....	3
6. SUMMARY OF THE CLAIMED SUBJECT MATTER.....	4
7. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL	7
8. ARGUMENT.....	9
10. APPENDICES	18
Claims Appendix	19
Evidence Appendix	24
Related Proceedings Appendix.....	25

2. REAL PARTY IN INTEREST

The real party in interest is Shlomo Gabbay.

3. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

4. STATUS OF CLAIMS

Independent claims 51, 62 and dependent claims 21-28, 52, 61-70, which are submitted herewith in the first Appendix, are currently pending in this Application.

Claims 1-20, 29-50 and 53-60 have been canceled. Claims 21, 28, 51, 61-63, 67 and 70 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,370,685 to Stevens (hereinafter "Stevens"). Claim 52 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,851,210 to Torossian (hereinafter "Torossian"). Claims 22-26, 65, 66, 68 and 69 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens in view of U.S. Patent No. 6,077,296 to Shokoohi et al. (hereinafter "Shokoohi"). Claim 27 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,851,210 to Vesely et al. (hereinafter "Vesely"). Claim 64 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,733,267 to Del Toro (hereinafter "Del Toro"). Independent claims 51, 62 and dependent claims 21-28, 52, 61-70 are being appealed.

5. STATUS OF AMENDMENTS

A Final Office Action (hereinafter the "Final Rejection") was issued on January 29, 2007. No response (or amendments) was filed in response to the Final Rejection. The

amendments contained in the response filed on November 1, 2006, were accepted. Thus, Appendix A submitted herewith contains a listing of claims in their currently pending form.

6. SUMMARY OF THE CLAIMED SUBJECT MATTER

a. Claim 27 (Depends from Claim 51)

Claim 27 is directed to the system (700 of FIG. 19) of claim 51, wherein the support further comprises an outer sheath (100 of FIG. 6B) of a substantially biocompatible material that covers the exposed parts of the support (Page 11, Lines 13-15).

b. Claim 28 (Depends from Claim 51)

Claim 28 is directed to the system (700 of FIG. 19) of claim 51, wherein the valve (702 of FIG. 19) further comprises a pulmonic animal heart valve (702 of FIG. 19) having leaflets (22, 24, 26 of FIG. 2) located within a valve wall to permit substantially unidirectional flow of blood through the valve (702 of FIG. 19), the support engaging an outer surface of the valve wall (Page 5, Lines 27-31 and Page 6, Lines 14-20).

c. Claim 51 (Independent)

One aspect of the invention as recited in claim 51, is directed to an implantation system (700 of FIG. 19) comprising an elongated cylindrical member (704 of FIG. 19) having spaced apart ends, at least one of the ends providing an opening (Page 26, Lines 29-31). The implantation system (700 of FIG. 19) also comprises a body portion from which the cylindrical member extends to terminate in the opening that is spaced longitudinally apart from the body portion (706 of FIG. 19) (Page 26, Lines 29-31). The system further comprises a body portion (706 of FIG. 19) having a greater outer

diameter than the cylindrical member (704 of FIG. 19) wherein the cylindrical member has an inner diameter in a range from about 5 mm to about 15 mm (Page 27, Lines 6-8). The system also comprises the cylindrical member (704 of FIG. 19) and body portion (706 of FIG. 19) being substantially coaxial along a linear axis extending through the cylindrical member (704 of FIG. 19) and the body portion. The system further comprising a heart valve prosthesis (702 of FIG. 19) including a generally cylindrical support having axially spaced apart ends (Page 28, Lines 22-23). The prosthesis (702 of FIG. 19) of the system further comprising a valve (754 of FIG. 21) mounted within the support (752 of FIG. 21) at a fixed axial position between the spaced apart ends of the support (752 of FIG. 21) (Page 29, Lines 29-30). The implantation system (700 of FIG. 19) further comprising the prosthesis (702 of FIG. 20) being deformable to a first condition in which the prosthesis has a reduced cross-sectional dimension (Page 27, Lines 2-5). The implantation system (700 of FIG. 19) further comprising the support (752 of FIG. 21) being biased to expand the prosthesis radially outward from the first condition to a second condition in which the prosthesis (702 of FIG. 19) has a cross-sectional dimension that is greater than the reduced cross-sectional dimension (Page 30, Lines 4-7). The implantation system (700 of FIG. 19) further comprises the prosthesis (702 of FIG. 19) being mounted within the cylindrical member in the first condition. Additionally, the implantation system (700 of FIG. 19) also comprises a plunger (750 of FIG. 21) operative to traverse at least part of the cylindrical member (704 of FIG. 19) and urge the prosthesis (702 of FIG. 19) from the cylindrical member through the opening (708 of FIG. 19) (Page 29, Lines 23-26).

d. Claim 52 (Depends from Claim 51)

Claim 52 is directed to the system (700 of FIG. 19) of claim 51, wherein the system further comprises indicia (710 of FIG. 19) along an exterior portion of the cylindrical member (704 of FIG. 19) to facilitate implantation of the heart valve prosthesis (702 of FIG. 19) (Page 27, Lines 11-13).

e. **Claim 62 (Independent)**

Another aspect of the invention as recited in claim 62, is directed to an implantation system (700 of FIG. 19) comprising an implanter comprising an elongated cylindrical member (704 of FIG. 19) having spaced apart ends and a lumen (Page 26, Lines 29-31). The implanter system (700 of FIG. 19) further comprises a body portion (706 of FIG. 19) having a greater outer diameter than the cylindrical member (704 of FIG. 19) (Page 27, Lines 6-8). The implanter system further comprises the cylindrical member (704 of FIG. 19) extending from the body portion (706 of FIG. 19) to terminate in the opening (708 of FIG. 19) spaced longitudinally apart from the body portion (706 of FIG. 19) (Page 26, Lines 29-31). The cylindrical member (704 of FIG. 19) and a body portion (706 of FIG. 19), being substantially coaxial along a linear axis that extends through the implanter (700 of FIG. 19). The implanter system (700 of FIG. 19) also comprising a plunger (716 of FIG. 19) operative to traverse at least part of the lumen along the linear axis (Page 27, Lines 23-25). The implanter system (700 of FIG. 19) further comprises a generally cylindrical support (752 of FIG. 21) having axially spaced apart ends (Page 30, Lines 1-4). The implanter system also comprising a valve (754 of FIG. 21) mounted within the support (752 of FIG. 21) (Page 29, Lines 29-30). The implanter system (700 of Fig. 19) additionally comprising the prosthesis (702 of FIG. 19) being deformable to a first condition in which the prosthesis has a reduced cross-

sectional dimension (Page 27, Lines 2-5). The implanter system (700 of FIG. 19) additionally comprising the prosthesis (702 of FIG. 19) being expandable from the first condition to a second condition in which the prosthesis has a cross-sectional dimension that is greater than the reduced cross-sectional dimension (Page 30, Lines 5-8). The implanter system (700 of FIG. 19) additionally comprises the prosthesis (702 of FIG. 19) being mounted within the cylindrical member in the first condition, such that the plunger (716 of FIG. 19) is operative to traverse at least part of the cylindrical member (704 of FIG. 19) and urge the prosthesis (702 of FIG. 19) from the cylindrical member (704 of FIG. 19) through the opening (708 of FIG. 19) (Page 29, Line 23-26).

f. **Claim 64 (Depends from Claim 62)**

Claim 64 is directed to the system (700 of FIG. 19) of claim 62, wherein the cylindrical enclosure (704 of FIG. 19) of the implanter (700 of FIG. 20) can have an inner diameter in a range from about 5 mm to about 15 mm, and the body portion (706 of FIG. 19) having a diameter that is greater than that of the cylindrical enclosure (704 of FIG. 20) (Page 27, Lines 6-8).

7. **GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

- a. Whether the rejection of claims 21, 28, 51, 61-63, 67 and 70 under 35 U.S.C. 103(a) as being made obvious by Stevens is proper.
- b. Whether the rejection of claim 52 under 35 U.S.C. 103(a) as being made obvious by Stevens in view Torossian is proper.
- c. Whether the rejection of claims 22-26, 65, 66, 68 and 69 under 35 U.S.C. 103(a) as being made obvious by Stevens in view of Shokoohi is proper.

- d. Whether the rejection of claim 27 under 35 U.S.C. 103(a) as being made obvious by Stevens in view Vesely is proper.
- e. Whether the rejection of claim 64 under 35 U.S.C. 103(a) as being made obvious by Stevens in view of Del Toro is proper.

8. ARGUMENT

A. The rejection of claims 21, 28, 51, 61-63, 67 and 70 under 35 U.S.C. 103(a) as being made obvious by Stevens is not proper.

The M.P.E.P. sets forth the criteria for a rejection for obviousness as follows:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure.

See, MPEP § 706.02(j) citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

i. The rejection of claim 51 and 62

It is respectfully suggested that the Final Rejection dated January 29, 2007 (hereinafter the "Final Rejection") fails to establish a *prima facie* case of obviousness with regard to claim 51 in view of Stevens for at least the following reasons:

The Final Rejection contends that claims 51 and 62 are made obvious by the structure shown and described in Stevens at FIGS. 9-13 (See Final Rejection, Pages 2-3). In particular, the Final Rejection alleges that an introducer channel (50) corresponds to the claimed cylindrical member and that a device capsule (14) corresponds to the body portion recited in claims 51 and 62. However, the introducer channel (50) does not extend from the device capsule to terminate in the opening, as claimed, nor is any prosthesis mounted within the introducer channel (50) of Stevens consistent with

claims 51 and 62. That is, in contrast to the allegations made in the Final Rejection, and the teachings of Stevens, claims 51 and 62 recite that the opening of an elongated cylindrical member is spaced longitudinally apart from a body portion (the body portion having a greater outer diameter than the cylindrical member) and a prosthesis is mounted within the cylindrical member.

Additionally, the interpretation of Stevens applied in the Final Rejection also fails to teach or suggest that the pusher disc (60) is operative to traverse part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening, in contrast to the plunger recited in claims 51 and 62. Instead, the pusher disc (60) of Stevens is shown and described as traversing the larger diameter device capsule in which a prosthetic valve device may be situated (See Stevens, FIG. 9 and Col. 8, Lines 6-7). Accordingly, claims 51 and 62 are not made obvious by Stevens.

Moreover, in the Final Rejection, it was admitted that Stevens fails to disclose that a cylindrical member extends to terminate in an opening spaced longitudinally apart from a body member (See Final Rejection, Page 3). However, it is stated in the Final Rejection that it would have been obvious to have a cylindrical member terminate apart from a body member (See Final Rejection, Page 3.) Appellant's representative respectfully submits that without any factual basis for support, the Final Rejection's statements are merely speculation. "Speculation is not sufficient for establishing a *prima facie* case of obviousness... a rejection based on §103, must rest upon a factual basis rather than conjecture, or speculation." *Ex Parte Yamamoto*, 57 U.S.P.Q.2d 1382, 1383 (B.P.A.I. 2001); citing *In re Warner*, 379 F.2d 1011, 1017, 154 U.S.P.Q. 173, 178 (CCPA 1967). The Examiner has failed to show reasons that the skilled

artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Moreover, since there has been no indication of any teaching or suggestion in the art of record to provide a system as recited in either of claims 51 and 62, the unsupported conclusion in the Office Action appears to be based on improper hindsight in which the present application is being used as a blueprint to provide the missing teaching or suggestion. *Id.*

For the reasons stated above, Stevens fails to make claims 51 and 62 obvious. Accordingly, reconsideration and allowance of claims 51 and 62 are respectfully requested.

ii. The rejection of claims 21 and 61

Claims 21 and 61 depend from claim 51 and are not made obvious by Stevens for at least the same reasons as claims 51 and for the specific elements recited therein. Accordingly, reconsideration and allowance of claims 21 and 61 is respectfully requested.

iii. The rejection of claim 28

Claim 28 depends from claim 51 and is not made obvious by Stevens for at least the same reason stated above with respect to claim 51, and for the following reasons. In the Final Rejection it is admitted that Stevens fails to disclose the use of a pulmonic animal heart valve, as recited in claim 28 (See Final Rejection, Page 3). Without the

benefit of any prior art teaching, the Final Rejection then goes on to conclude that it would have been an obvious matter of design choice to modify the type of valve used in Stevens to a pulmonic valve. Appellant submits that a heart valve prosthesis and implanter combination recited in claim 28, including a pulmonic valve, has structural and functional features (e.g., generally soft and substantially thin cusps), which, for certain applications, has a propensity for improved valve function and longevity, when compared to many other types of valves (e.g., as disclosed in Stevens). These advantages, which the Court of Appeals for the Federal Circuit mandates must be considered, demonstrate non-obviousness of claim 28 over Stevens and the approaches disclosed in the other art of record. *In re Chu*, 66 F.3d 292, 34 U.S.P.Q.2d 1089 (Fed. Cir. 1995).

Appellant's representative respectfully submits that the absence of any teaching of employing a pulmonic valve in the type of heart valve prosthesis being claimed in claim 28 further weighs on the side of non-obviousness, as it demonstrates the failure of those skilled in the art to appreciate the potential benefits of using a pulmonic valve in the system of claim 28. See, for example, *Arkie Lures Inc. v. Gene Larew Tackle Inc.*, 119 F.3d 953, 957, 43 U.S.P.Q.2d 1294, 1297 (Fed. Cir. 1997), where the Court held that when elements have co-existed for many years and never combined weighs on the side of non-obviousness. Similar to the situation in *Arkie Lures*, *supra*, claim 28 represents a solution to a problem (an implantation system that affords efficient implantation of a competent heart valve prostheses) for which there is long felt but unmet need. This becomes clearer when the teachings of Stevens are considered as a whole.

It is asserted in the Final Rejection that one of ordinary skill in the art "would have expected Appellant's invention to perform equally well with the type of valve chosen as taught by Stevens such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 28 because both heart valve prostheses perform the same function..." (See Final Rejection, Pages 3-4). However, the Final Rejection fails to identify a legal basis (statute, rule or legal precedent) to support how an expectation of one skilled in the art about the performance of the system recited in claim 28, if the structure of claim 28 were modified to use a valve taught by Stevens, would affect patentability of claim 28. This contention thus appears to rely explicitly on improper hindsight to support an obviousness conclusion.

For the reasons described above, claim 28 is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

iii. The rejection of claims 63, 67 and 70

Claims 63, 67 and 70 depend either directly or indirectly from claim 62 and are not made obvious by Stevens for at least the same reasons as claims 62 and for the specific elements recited therein. Accordingly, reconsideration and allowance of claims 63, 67 and 70 is respectfully requested.

B. The Rejection of claim 52 under 35 U.S.C. 103(a) as being made obvious by Stevens in view of Torossian is improper.

Claim 52 depends from claim 51. The addition of Torossian does not make up for the aforementioned deficiencies of Stevens with respect to claim 51, from which claim 52 depends. Additionally, the purported combination of Stevens and Torossian fails to teach or suggest the subject matter recited in claim 52. In particular, nothing in Torossian or in Stevens suggests or provides motivation to one of ordinary skill in the art to utilize the markers of Torossian on the type of implanter configured as recited in claim 51. For this reason, an individual reasonably skilled in the art would not consider the subject matter recited in claim 52 obvious in light of prior art, namely the combination of Torossian and Stevens. Since claim 51 is individually patentable over Stevens, alone as well as in combination with other art of record for the reasons stated herein above, claim 52 which depends respectively from claims 51 is also allowable.

For the reasons described above, claim 52 is patentable over Steven taken in view of Torossian. Accordingly, reconsideration and allowance of claim 52 is respectfully requested.

C. The Rejection of claims 22-26, 65, 66, 68 and 69 under 35 U.S.C. §103(a) as being made obvious by Stevens in view of Shokoohi is improper.

Claims 22-26, 65, 66, 68 and 69 depend from claims 51 and 62. The addition of Shokoohi does not make up for the aforementioned deficiencies of Steven discussed above with respect to claims 51 and 62, from which claims 22-26, 65, 66, 68 and 69 depend. In particular, as mentioned above, Stevens, alone or in combination with Shokoohi or any other cited reference, still fails to teach or suggest the structural and functional interrelationships of claim 51 from which claims 22-26 depend. In contrast to

claims 51 and 62 and to claims 22-26, 65, 66, 68 and 69, Shokoohi discloses an endolumenal support for supporting a vascular lumen such as arteries (see Shokoohi, Abstract, and Col. 2, lines 44-49), but fails to teach or suggest any applicability to use as a support for a heart valve in an implantation system, as recited in the pending claims. Therefore, if Shokoohi is combined with Stevens, as suggested in the Final Rejection, it is respectfully submitted that the combination still fails to teach or suggest the subject matter recited in claims 22-26. As mentioned above, Stevens, alone or in combination with Shokoohi or any other cited reference, still fails to teach or suggest the structural and functional interrelationships of claim 51 from which claims 22-26 depend. Shokoohi further includes no teaching or suggestion that would enable one of ordinary skill in the art to mount a valve in the support taught by Shokoohi, as recited in claims 22-26.

Moreover, claims 65, 66, 68 and 69 which depend from claim 62, are patentable for at least substantially the same reasons, and their allowance is respectfully requested.

For at least the reasons stated above, claims 22-26, 65, 66, 68 and 69 are patentable. Accordingly, reconsideration and allowance of claims 22-26, 65, 66, 68 and 69 are respectfully requested.

D. The Rejection of claims 27 Under 35 U.S.C. §103(a) as being made obvious by Stevens in view of Vesely is not proper.

Claim 27 depends from claim 51. The addition of Vesely does not make up for the aforementioned deficiencies of Stevens stated above with respect to claim 51, from which claim 27 depends.

Moreover, it was contended in the Final Rejection that it would be obvious to use a cloth covering (35) as taught by Vesely in the prosthetic valve device of Stevens (See Final Rejection, Page 5). However, the addition of Vesely does not cure the deficiencies of Stevens, as discussed above. Additionally, the reasons for motivation of including the cloth covering (35) in the prosthetic valve device of Stevens appear to be based on improper hindsight or based on assertions not supported in the references. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). Appellant's representative respectfully submits that the Final Rejection has used claim 27 as the aforementioned template to support a finding of obviousness. Accordingly, claim 27 is not made obvious by Stevens taken in view of Vesely.

For at least the reasons discussed above, claim 27 is patentable. Thus, reconsideration and allowance of claim 27 is respectfully requested.

E. The Rejection of claim 64 Under 35 U.S.C. §103(a) as being made obvious by Stevens in view of Del Toro is not proper.

Claim 64 depends from claim 62. The addition of Vesely does not make up for the aforementioned deficiencies of Stevens stated above with respect to claim 62, from

which claim 64 depends. Additionally, the Final Rejection relies on Del Toro for a purported teaching of a handle (See Final Rejection, Page 5). Contrary to the contention in the Final Rejection, Del Toro, does not teach or suggest a handle portion attached to the body portion at a position near a substantially opposite end of the body portion from which the cylindrical member extends, as recited in claim 64. Instead, Del Toro discloses a manifold stabilizer 40 (not a handle) that operates to hold the inner shaft 36 in position during pull back of a middle pull back shaft 34 to further prevent flattening of the outside the body arc or the inside the body arc during deployment (See Del Toro at Col. 3, Lines 17-29). There is no motivation to add such a stabilizer 40 to any part of the device taught in Stevens, especially not extending from either the bracer (70) of Stevens or from the device capsule (14), which the Examiner has interpreted as could correspond to the body portion recited in claim 62. Such a contention would require inserting the alleged stabilizer (40) into the implantation site since Stevens, however, discloses both such parts as being used in endovascular valve replacement, such that there would be no motivation to include any handle or include a stabilizer, as taught by Del Toro (See Stevens, Col. 4, Line 59, through Col. 5, Line 28). Accordingly, Stevens taken in view of Del Toro fails to make claim 64 obvious. Therefore, reconsideration and allowance of claim 64 is respectfully requested.

10. APPENDICES

Appendix A submitted herewith is a claims appendix containing a copy of the claims on appeal.

Appendix B submitted herewith is an evidence appendix.

Appendix C submitted herewith is a related proceedings appendix.

In the event any additional fees are due in connection with the filing of this document, including for any extensions of time, the Commissioner is authorized to charge those fees to our Deposit Account No. 20-0090.

Respectfully submitted,

TAROLLI, SUNDHEIM, COVELL & TUMMINO LLP



Gary J. Pitter
Reg. No. 39,334

CUSTOMER NO.: 26,294
526 Superior Avenue
1111 Leader Building
Cleveland, Ohio 44114
Telephone: (216) 621-2234 x106
Facsimile: (216) 621-4072

Claims Appendix

Claim 21 The system of claim 51, the support being formed of a shape memory alloy operative to urge the prosthesis to the second condition.

Claim 22 The system of claim 51, the support further comprising a plurality of elongated support features that extend generally axially between ends of the support, biasing elements interconnecting adjacent support features in a circumscribing relationship around the valve, the biasing elements urging the interconnected adjacent support features apart from each other, so as to urge the prosthesis toward the second condition.

Claim 23 The system of claim 22, further comprising at least one connecting element operative to hold the biasing elements in a generally circular array and to limit the radial outward expansion of the prosthesis at the location of the circular array.

Claim 24 The system of claim 22, further comprising a plurality of resilient projections that extend radially outwardly from the axially opposed ends of the support.

Claim 25 The system of claim 24, the projections further comprising a set of triangular projections attached to each of the opposed ends of the support by biasing elements that bias the triangular projections to extend axially and radially outwardly from each of the respective opposed ends of the support.

Claim 26 The system of claim 22, the support features and the biasing elements being formed of a continuous length of a substantially resilient and elastic

material that facilitates expansion of the prosthesis from the first condition to the second condition.

Claim 27 The system of claim 51, further comprising an outer sheath of a substantially biocompatible material that covers exposed parts of the support.

Claim 28 The system of claim 51 wherein the valve further comprises a pulmonic animal heart valve having leaflets located within a valve wall to permit substantially unidirectional flow of blood through the valve, the support engaging an outer surface of the valve wall.

Claim 51 An implantation system, comprising:

an elongated cylindrical member having spaced apart ends, at least one of the ends providing an opening;

a body portion from which the cylindrical member extends to terminate in the opening that is spaced longitudinally apart from the body portion, the body portion having a greater outer diameter than the cylindrical member, the cylindrical member having an inner diameter in a range from about 5 mm to about 15 mm, the cylindrical member and body portion being substantially coaxial along a linear axis extending through the cylindrical member and the body portion;

a heart valve prosthesis including a generally cylindrical support having axially spaced apart ends, a valve mounted within the support at a fixed axial position between the spaced apart ends of the support, the prosthesis being deformable to a first condition in which the prosthesis has a reduced cross-sectional dimension, the support being biased to expand the prosthesis radially outwardly from the first condition to a

second condition in which the prosthesis has a cross-sectional dimension that is greater than the reduced cross-sectional dimension, the prosthesis being mounted within the cylindrical member in the first condition; and

a plunger operative to traverse at least part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening.

Claim 52 The system of claim 51, further comprising indicia along an exterior portion of the cylindrical member to facilitate implantation of the heart valve prosthesis.

Claim 61 The system of claim 51, wherein the valve comprises a natural tissue heart valve mounted within the support.

Claim 62 An implantation system, comprising:

an implanter comprising:

an elongated cylindrical member having spaced apart ends and a lumen extending through the cylindrical member, at least one of the ends providing an opening into the lumen;

a body portion having a greater outer diameter than the cylindrical member, the cylindrical member extending from the body portion to terminate in the opening spaced longitudinally apart from the body portion, the cylindrical member and body portion being substantially coaxial along a linear axis that extends through the implanter;

a plunger operative to traverse at least part of the lumen along the linear axis; and

a heart valve prosthesis comprising:

a generally cylindrical support having axially spaced apart ends, and
a valve mounted within the support, the prosthesis being deformable to a
first condition in which the prosthesis has a reduced cross-sectional dimension and
being expandable from the first condition to a second condition in which the prosthesis
has a cross-sectional dimension that is greater than the reduced cross-sectional
dimension, the prosthesis being mounted within the cylindrical member in the first
condition, such that the plunger is operative to traverse at least part of the cylindrical
member and urge the prosthesis from the cylindrical member through the opening.

Claim 63 The implantation system of claim 62, the cylindrical member of the
implanter having an inner diameter in a range from about 5 mm to about 15 mm, and
the body portion having a diameter that is greater than that of the cylindrical enclosure.

Claim 64 The implantation system of claim 62, the implanter further
comprising a handle portion attached to and extending radially outwardly from the body
portion at a position that is spaced axially from an end of the body portion from which
the cylindrical member enclosure extends.

Claim 65 The implantation system of claim 63, wherein the support of the
prosthesis further comprises axially extending support features interconnected by
biasing elements that bias the support to expand radially outwardly from the first
condition to the second condition.

Claim 66 The implantation system of claim 65, the biasing elements further
comprising springs arranged in a generally circular array at the opposed ends of the

support, the springs interconnecting adjacent support features to bias the support radially outwardly.

Claim 67 The implantation system of claim 62, wherein the valve comprises a natural tissue heart valve mounted within the support.

Claim 68 The implantation system of claim 62, the prosthesis further comprising a flexible connecting element attached to the support to inhibit radial outward expansion of at least part of the support beyond a predetermined amount.

Claim 69 The implantation system of claim 68, the prosthesis further comprising a loop of a flexible material connected to the support at each of the axially spaced apart ends to inhibit radial outward expansion of the support at the opposed ends beyond a predetermined amount.

Claim 70 The implantation system of claim 63, the prosthesis further comprising projections biased to extend radially outwardly from the support.

Evidence Appendix

None.

Related Proceedings Appendix

None